DYNACEF SUSPENSION

SCHEDULING STATUS S4

1. NAME OF THE MEDICINE
DYNACEF SUSPENSION 40 mg/5 mL, powder for oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5 mL of suspension contains cefpodoxime proxetil equivalent to cefpodoxime 40 mg.
DYNACEF SUSPENSION contains sugar (sucrose 2,46 g/5 mL). Contains sweetener (aspartame 20 mg/5 mL).
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Powder for oral suspension.
Powder: Almost white to pale yellow coloured powder.
Reconstituted solution: Off-white to pale yellow suspension with characteristic fruity odour.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
In Children:
DYNACEF SUSPENSION is indicated for use in the short-term treatment of upper and lower respiratory tract infections caused by susceptible micro-organisms:
- acute otitis media due to: *Haemophilus influenzae* (non-typeable), *Streptococcus pneumoniae*, *Moraxella catarrhalis*
- tonsillitis and pharyngitis due to: *Streptococcus pyogenes*
- pneumonia due to: *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Moraxella catarrhalis*.

4.2 Posology and method of administration
Posology
Paediatric population
The dosage depends on the weight of the child being treated. The average dose is 8 mg/kg/day. The following may be used as a dosage guide:
- children weighing between 10 and 15 kg the dose is 5 mL (40 mg) every 12 hours
- children weighing 15 kg or more, the dose is 10 mL (80 mg) every 12 hours.

The use of DYNACEF SUSPENSION in children under one year of age has not been established (see section 4.3).

DYNACEF SUSPENSION must not be given to children with phenylketonuria, since the formulation contains aspartame (see section 4.3).

Refer to section 6.6 for reconstitution instructions.

Special populations
Renal Insufficiency in children:
When the creatinine clearance is above 40 mL/min, it is not necessary to adjust the dose. For values below 40 mL/min, the daily dosage regimen should be reduced by half. For values 10 - 39 mL/min DYNACEF SUSPENSION should be administered as a single daily dose and every second day for values below 10 mL/min. DYNACEF SUSPENSION should be administered after each dialysis session for haemodialysis patients.

Hepatic insufficiency in children:
No dosage adjustment necessary.

Method of administration
Oral use.
DYNACEF SUSPENSION is administered in two doses at 12 hourly intervals with meals. Shake the bottle before use.
Refer to section 6.6. for reconstitution instructions.

Missed dose:
Medical practitioners should advise patients who forget to take DYNACEF SUSPENSION to take a dose as soon as possible and then continue with the normal dose. Patients should not take a double dose to compensate for the missed dose.

4.3 Contraindications
DYNACEF SUSPENSION is contraindicated in:
- known sensitivity to cephalosporin antibiotics, penicillin's, any other beta-lactam class of antibiotics, or to any of the ingredients of DYNACEF SUSPENSION (see section 6.1)
- DYNACEF SUSPENSION must not be given to children with phenylketonuria since the formulation contains aspartame.
- children below 1 year of age (see section 4.2).

4.4 Special warnings and precautions for use
Hypersensitivity reactions:
Before initiating therapy with DYNACEF SUSPENSION, careful enquiry should be made concerning an allergic diathesis and previous hypersensitivity reactions to penicillin and other beta-lactam antibiotics.

The use of DYNACEF SUSPENSION is strictly contraindicated in subjects with a previous history of immediate type hypersensitivity to cephalosporins (see section 4.3).

There have been reports of serious and occasionally fatal hypersensitivity reactions which progressed to Kounis syndrome (acute allergic coronary arterio-spasm that can result in myocardial infarction) (see section 4.8). If an allergic reaction occurs, treatment should be stopped immediately.

***Clostridium difficile*-associated disease:**
Prolonged use may result in overgrowth of non-susceptible organisms.
Pseudomembranous colitis may develop. It is important to consider its diagnosis in patients who develop diarrhoea, particularly if severe and/or persistent in association with the use of DYNACEF SUSPENSION. Such colitis may range in severity from mild to life threatening. Treatment should be discontinued if symptoms suggestive of pseudomembranous colitis arise. Mild cases of pseudomembranous colitis usually respond to discontinuance of the medicine alone.
The diagnosis of this possibly fatal condition is confirmed by endoscopy and/or histology. Screening of faeces for this pathogen, and its cytotoxin is the best way to diagnose *Clostridium difficile*-associated disease.
When the colitis or suspected pseudomembranous colitis, does not improve after the medicine has been discontinued, or when it is severe, oral vancomycin or metronidazole therapy should be started without delay.
Clostridium difficile-associated disease can be favoured by faecal stasis.

Renal impairment:
DYNACEF SUSPENSION should be given with caution to patients with renal impairment. In patients with severe renal failure, it may be necessary to adjust the daily dose based on creatinine clearance (see section 4.2).

Changes in renal function have been observed with antibiotics of the same class and particularly when given concurrently with potentially nephrotoxic agents such as aminoglycosides and/or potent diuretics. In such cases renal function should be monitored.

Interactions with laboratory tests:
DYNACEF SUSPENSION may interfere with Jaffe method of measuring creatinine concentrations and may produce falsely high values.

Positive Coombs test:
DYNACEF SUSPENSION may be absorbed onto the surface of red cell membranes and react with antibiotics directed against the medicine. This can produce a positive antiglobulin test and haemolytic anaemia. Cross-reactivity may occur with penicillin for this reaction.

Superinfection:
The use of DYNACEF SUSPENSION, especially if prolonged, may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential. If superinfection occurs during therapy, appropriate measures should be taken (see section 4.8).

Encephalopathy:
Beta-lactam antibiotics, including cefpodoxime (as in DYNACEF SUSPENSION), predispose patients to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness or movement disorders), particularly in case of overdose or if they have impaired renal function.

Information on excipients of DYNACEF SUSPENSION:
Aspartame:
DYNACEF SUSPENSION contains aspartame (20 mg/5 mL).
Excessive use of aspartame should be avoided by patients with phenylketonuria since one of its metabolic products is phenylalanine (see section 4.3).

Sucrose:
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Sodium benzoate:
Increase in bilirubinaemia following its displacement from albumin may increase neonatal jaundice which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue).

4.5 Interaction with other medicines and other forms of interaction
- probenecid slows tubular excretion of DYNACEF SUSPENSION and increases serum levels thereof
- the bioavailability increases if DYNACEF SUSPENSION is administered during meals (acidic pH)
- absorption of DYNACEF SUSPENSION is decreased by concurrent ingestion of antacids or histamine H_2-receptor antagonists such as ranitidine. Therefore, mineral antacids (aluminium hydroxide, sodium bicarbonate) and histamine blocking H_2 blockers, which cause an increase in gastric pH, should be taken 2 or 3 hours after DYNACEF SUSPENSION administration. In contrast, a decrease in gastric pH (caused by pentagastrin) will increase bioavailability
- enhanced nephrotoxicity with a loop diuretic (e.g. furosemide) may occur
- changes in renal function have been observed with antibiotics of the same class, particularly when given concurrently with potentially nephrotoxic medicines such as aminoglycosides (e.g. gentamicin) and/or potent diuretics. In such cases, renal function should be monitored (see section 4.2)
- as with other cephalosporins, isolated cases showing development of a positive Coombs test have been reported (see section 4.4)
  In patients treated with DYNACEF SUSPENSION, a false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions
- concurrent use with anticoagulants, such as warfarin, may increase the risk of bleeding.

Special international normalised ratio (INR) imbalance issues
Numerous cases of increased oral anticoagulant activity have been reported in patients receiving antibiotics. The severity of the infection or inflammation, age and general health status of the patient appear to be risk factors. Under these circumstances, it seems difficult to determine to what extent the infection itself or its treatment play a role in the INR imbalance. However, certain classes of antibiotics are more involved, particularly fluoroquinolones, macrolides, cyclines, cotrimoxazole and certain cephalosporins.

4.6 Fertility, pregnancy and lactation
Not applicable.

4.7 Effects on ability to drive and use machines
If adverse effects occur, such as dizziness or encephalopathy (which can include seizure, confusion, consciousness disorders or abnormal movements), (see sections 4.4, 4.8, 4.9), patients should not drive or use machines.

4.8 Undesirable effects
a. Tabulated list of adverse effects

System Organ Class	Frequency	Side effects
Infections and Infestations	*Frequent*	Oral and vaginal candidiasis, superinfections, overgrowth of non-susceptible organisms
Blood and lymphatic system disorders	*Less frequent*	Thrombocytopenia, leucopenia, neutropenia, hypoprothrombinaemia, haemolytic anaemia, reduction of haemoglobin, thrombocytosis and agranulocytosis, aplastic anaemia, pancytopenia, eosinophilia, lymphocytosis, anaemia, leukocytosis eosinophilia,
Immune system disorders	*Less frequent*	Hypersensitivity reactions, anaphylactic reactions, angioedema, bronchospasm, malaise, shock
Metabolism and nutrition disorders	*Frequent*	Appetite loss
Nervous system disorders	*Frequent*	Headache
	Less frequent	Dizziness, paraesthesia, asthenia, seizures, CNS toxicity
Ear and labyrinth disorders	*Less frequent*	Tinnitus, hearing loss
Cardiac disorders	*Frequency unknown*	Kounis syndrome
Gastrointestinal disorders	*Frequent*	Diarrhoea, nausea, vomiting and abdominal pain
	Less frequent	Dyspepsia, flatulence, pseudomembranous colitis, blood in stools, acute pancreatitis, fever
Hepato-biliary disorders	*Less frequent*	Hepatic dysfunction including cholestasis, elevated liver enzymes (elevations of AST, ALT and alkaline phosphatase), bilirubinaemia, liver injury, hepatitis, cholestatic jaundice
Skin and subcutaneous tissue disorders	*Less frequent*	Pruritus and urticaria, toxic epidermal necrolysis, erythema multiforme, rash, Stevens-Johnson syndrome, bullous eruptions, cutaneous eruptions, purpura, Linear IgA bullous dermatosis (LABD)
Renal and urinary disorders	*Less frequent*	Renal dysfunction, toxic nephropathy, increase in blood urea and creatinine
General disorders and administrative site conditions	*Less frequent*	Fatigue and asthenia
Investigations	*Less frequent*	Positive response to the Coombs test

b. Description of selected adverse reactions
Beta-lactam antibiotics, including cefpodoxime (as in DYNACEF SUSPENSION, predispose patients to encephalopathy (which can include seizure, confusion, consciousness disorders or abnormal movements), particularly if they have had an overdose or if they have renal failure.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

4.9 Overdose
Signs and symptoms:
Overdosage with DYNACEF SUSPENSION may manifest in any of the symptoms described under section 4.8. Convulsions and other signs of central nervous system (CNS) toxicity have been associated with high doses, especially in patients with severe renal impairment. There is a risk of encephalopathy, particularly in patients with renal insufficiency.

Management of overdose:
There is no specific antidote for DYNACEF SUSPENSION.
Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Other beta-lactam antibacterials – Third-generation cephalosporins
ATC code: J01DD13
Pharmacological classification: A.20.1.1 Broad and medium spectrum antibiotics.

Mechanism of action
Cefpodoxime proxetil is a semi-synthetic beta-lactam antibiotic belonging to the third-generation oral cephalosporin group. Cefpodoxime proxetil is the prodrug of the bactericidal antibiotic cefpodoxime. Cefpodoxime possesses *in vitro* bactericidal activity against a broad spectrum of Gram positive and Gram-negative bacteria. *In vitro* sensitivity does not necessarily imply *in vivo* efficacy. The antibacterial action of cefpodoxime is through inhibition of bacterial cell wall biosynthesis most likely by acylation of membrane bound transpeptidase enzymes. This prevents cross linkage of peptidoglycan chains, which is necessary for bacterial cell wall strength and rigidity.

The following organisms are not sensitive: Group D streptococci, Methicillin-resistant staphylococci *(S. aureus and S. epidermidis)*, *Staphylococcus saprophyticus*, Corynebacteria, groups J and K, *Listeria monocytogenes*, *Pseudomonas aeruginosa* and *Pseudomonas* spp., *Acinetobacter baumannii*, *Clostridium difficile*, *Bacteroides fragilis* and related species.

5.2 Pharmacokinetic properties
The bioavailability of cefpodoxime proxetil is increased when the product is administered with meals, or when there is a decrease in gastric pH. Absorption is decreased in conditions of low gastric acidity.

Absorption:
Cefpodoxime proxetil is absorbed orally and rapidly hydrolysed by non-specific esterases in the gastrointestinal wall to cefpodoxime, the active acid.

Paediatric population:
After oral administration of a single 5 mg/kg dose (200 mg maximum) of cefpodoxime to subjects between 4 and 12 years of age, the maximum plasma concentration (C_{max}) is on average 2,6 mg/L. The time taken to reach maximum concentration (T_{max}) is 2 - 4 hours. The average plasma concentrations observed 8 and 12 hours after administration (residual) are 0,39 and 0,08 mg/L respectively.

Diffusion in fluids and tissues:
Cefpodoxime proxetil diffuses well in lung parenchyma, bronchial mucosa, pleural fluid and tonsils.

Metabolism and elimination:
The main metabolite is cefpodoxime, resulting from the hydrolysis of cefpodoxime proxetil. The serum half-life is about 2,4 hours. Clearance is about 2,4 mL/min/kg. Approximately 80 % of cefpodoxime is excreted unchanged in the urine.

5.3 Preclinical safety data
Not applicable

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Anhydrous citric acid (for pH adjustment)
Artificial banana flavour spray dry
Aspartame
Hydroxypropyl cellulose
Maize starch
Microcrystalline cellulose & carboxymethyl cellulose sodium
Silica colloidal anhydrous
Sodium benzoate
Spectracol yellow iron oxide
Sucrose.

6.2 Incompatibilities
Not applicable

6.3 Shelf life
2 years

6.4 Special precautions for storage
Before reconstitution:
Store at or below 25 °C, protect from light and humidity.

After reconstitution:
Use within 10 days. Store in a refrigerator (2 - 8 °C).
Shake well before use.
Keep the bottle tightly closed. Discard any unused portion. Do not freeze.

6.5 Nature and contents of container
Translucent HDPE bottle with a white polypropylene 28 mm cap (child resistant, with foil seal peelable liner), containing powder for reconstitution up to 50 mL or 100 mL of suspension, contained in a printed outer carton.

6.6 Special precautions for disposal and other handling
Directions for Reconstitution of the Suspension:
Remove the screw cap by simultaneously pushing and turning it. Remove the tear-tab and discard.
Add 27,0 mL water into the dry powder for the 50 mL suspension. Add 54,0 mL water in two equally divided portions to the dry powder for the 100 mL suspension. Shake well after each addition.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
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Silverwood Close
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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

DYNACEF SUSPENSION 40 mg/5 mL, powder for oral suspension
Cefpodoxime
DYNACEF SUSPENSION contains sugar (sucrose 2,46 g/5 mL).
Contains sweetener (aspartame 20 mg/5 mL).

Read all of this leaflet carefully before you start taking DYNACEF SUSPENSION
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- DYNACEF SUSPENSION has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DYNACEF SUSPENSION is and what it is used for
DYNACEF SUSPENSION belongs to the antibiotic group of medicines known as cephalosporins.

DYNACEF SUSPENSION is used in children for the treatment of:
- ear infection
- tonsilitis, throat infection (pharyngitis)
- pneumonia.

2. What you need to know before you administer DYNACEF SUSPENSION
Do not administer DYNACEF SUSPENSION:
- if your child is hypersensitive (allergic) to other cephalosporin antibiotics, penicillin, any other beta-lactam class of antibiotics or to any of the ingredients of DYNACEF SUSPENSION (see section 6)
- DYNACEF SUSPENSION must not be given to children with phenylketonuria (a rare inherited disorder that causes an amino acid called phenylalanine to build up in your body) since the formulation contains aspartame
- if your child is under 1 year old.

Warnings and precautions
Take special care with DYNACEF SUSPENSION:
- DYNACEF SUSPENSION should be taken with caution in patients who are generally allergic. Please tell your doctor about all allergic reactions your child may have had previously, especially to medicines
- if your child is allergic to penicillin antibiotics, as he/she may have an increased chance of being allergic to cephalosporins (including DYNACEF SUSPENSION) as well
- if your child has or has ever had a condition called colitis (inflammation of the large intestine with symptoms of abdominal pain, diarrhoea and fever) or if your child develops diarrhoea, particularly if severe and/or persistent while using DYNACEF SUSPENSION. This may be an indication of inflammation of the large intestine (colitis). Please consult your doctor immediately
- if your child has kidney problems (his/her dose may need to be adjusted)
- if your child undergoes certain blood or urine tests as DYNACEF SUSPENSION may interfere with the results
- if your child experiences symptoms such as convulsions, confusion, impairment of consciousness or movement disorders (especially in children with kidney problems or who have been given more medicine than required), contact your doctor or healthcare provider immediately.

Other medicines and DYNACEF SUSPENSION
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.) Certain medicines may interact with DYNACEF SUSPENSION. In these cases, it may be necessary to change the dose or interrupt the treatment of one of the medicines.
DYNACEF SUSPENSION works better when taken with food.

Medicines that may interact with DYNACEF SUSPENSION are:
- medicines used to treat ulcers such as ranitidine or cimetidine and antacids (used to treat indigestion such as aluminium hydroxide, sodium bicarbonate) may delay how DYNACEF SUSPENSION works
- pentagastrin (medicine used to stimulate stomach acid secretion) may increase the effects of DYNACEF SUSPENSION
- probenecid (used for the treatment of gout) may increase the blood levels of DYNACEF SUSPENSION and increase the chance of side effects
- anti-coagulants such as warfarin (used to thin the blood) may increase the risk of bleeding
- please ensure that your doctor knows that your child is taking DYNACEF SUSPENSION if he/she is required to take any tests (blood, urine or diagnostic), as this medicine may interfere with the test results
- certain diuretics (water tablets e.g. furosemide) used to increase the amount of urine you pass, may affect your kidneys
- aminoglycoside antibiotics (e.g. gentamicin) (used to treat infections) may affect the way your kidneys work
- as anti-coagulants may increase the risk of bleeding, your doctor may want to monitor increased ratio of the blood clotting time whilst your child is taking DYNACEF SUSPENSION.

DYNACEF SUSPENSION with food and drink
DYNACEF SUSPENSION must be administered after a meal.

Pregnancy and breastfeeding
Not applicable.

Driving and using machines
If adverse effects occur, such as dizziness or encephalopathy (which can include seizure, confusion, consciousness disorders or abnormal movements), patients should not drive or use machines.

It is not always possible to predict to what extent DYNACEF SUSPENSION may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DYNACEF SUSPENSION affects them.

DYNACEF SUSPENSION contains aspartame (20 mg/5 mL), sucrose and sodium benzoate.
Aspartame:
DYNACEF SUSPENSION should not be taken by patients with phenylketonuria since one of its metabolic products is phenylalanine (see Do not take DYNACEF SUSPENSION).

Sucrose:
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DYNACEF SUSPENSION. This should be taken into account in patients with diabetes mellitus.

Sodium benzoate:
DYNACEF SUSPENSION contains 10 mg sodium benzoate in 5 mL suspension, which is equivalent to 0,2 %.
Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to administer DYNACEF SUSPENSION
Do not share medicines prescribed for you with any other person. Always administer DYNACEF SUSPENSION exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
DYNACEF SUSPENSION must be taken after a meal.

Children:
The average dose is 8 mg/kg/day administered in two doses every 12 hours with meals. Your doctor will adjust the dose according to the child's weight.

The following may be used as a dosage guide:
- children weighing between 10 and 15 kg the dose is 5 mL every 12 hours
- children weighing 15 kg or more, the dose is 10 mL every 12 hours.

Shake the bottle before use. For reconstitution instructions, refer to section 6.

Kidney disorders:
If your child has a kidney disorder, he/she will receive lower doses than the normal dose. Your doctor will determine the correct dose according to his/her condition.

DYNACEF SUSPENSION must not be given to children with phenylketonuria, since the formulation contains aspartame (see Do not take DYNACEF SUSPENSION).

Administration of DYNACEF SUSPENSION in children under one year of age is currently not indicated as safety has not yet been established.

Your doctor will tell you how long your child's treatment with DYNACEF SUSPENSION will last.
If you have the impression that the effect of DYNACEF SUSPENSION is too strong or too weak, tell your doctor or pharmacist.

If you administer more DYNACEF SUSPENSION than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
Take this leaflet and any remaining suspension with you, so that the doctor knows what medicine your child has taken.

Symptoms of overdose may include:
- any of the symptoms as described under Side Effects including central nervous system toxicity (with symptoms including anxiety, dizziness, mouth numbness, light-headedness, ringing or buzzing in the ears and convulsions) and brain function (with symptoms such as memory loss, personality change, seizures and twitching).

If you forget to administer DYNACEF SUSPENSION
If you forget to administer DYNACEF SUSPENSION, administer it as soon as you remember on the same day. If you do not administer a dose on that same day, give the normal dose the next day. Do not administer a double dose to make up for forgotten individual doses.

If you stop the use of DYNACEF SUSPENSION
It is important that you continue the course of treatment even if your child begins to feel better after a few days.

4. Possible side effects
DYNACEF SUSPENSION can have side effects.
Not all side effects reported for DYNACEF SUSPENSION are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using DYNACEF SUSPENSION, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using DYNACEF SUSPENSION and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, shock
- rash or itching
- fainting.

These are all very serious side effects. If your child has them, they may have had a serious allergic reaction to DYNACEF SUSPENSION. Your child may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- hepatitis (inflammation of the liver) and other liver problems including jaundice (symptoms may include: nausea, vomiting, stomach pain, loss of appetite, tiredness, yellowing of the skin or whites of your eyes, dark urine), liver injury, increased liver enzymes
- a severe infection of the lining of the bowel, characterised by diarrhoea, fever and abdominal pain. This may be something called 'Pseudomembranous colitis', blood in stools
- blistering, peeling or bleeding on any part of your skin with or without a rash (including your lips, eyes, mouth, nose, genitals, hands or feet), flu-like symptoms (fever, chills or aching muscles) which are symptoms of a serious skin reaction (Stevens-Johnson syndrome or toxic epidermal necrolysis (TEN)) which could be fatal
- skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious skin allergy called 'erythema multiforme'
- pancreatitis (inflammation of the pancreas) (symptoms may include upper abdominal pain that radiates into the back; swollen and tender abdomen; nausea and vomiting, fever and increased heart rate)
- your child gets infections more easily than usual. This could be because of a blood disorder and is more likely if he/she taking DYNACEF SUSPENSION for a long time
- superinfection (a second infection which occurs during the course of the existing infection, by other bacteria or organisms resistant to DYNACEF SUSPENSION), including fungal infections such as oral or vaginal thrush
- chills, tiredness, unusually pale skin colour, shortness of breath, fast heartbeat or dark coloured urine. These could be signs of a serious type of anaemia
- blood disorders which may make your child more likely to get infections, get tired very easily, or bruise very frequently
- your child bruises more easily than usual, or may have a painful rash of dark red spots under the skin which do not go away when you press on them (purpura). This could be because of a serious blood problem
- seizures, central nervous system toxicity (with symptoms including anxiety, dizziness, mouth numbness, light-headedness, ringing or buzzing in the ears and convulsions)
- little or no urine when you try to urinate, decreased kidney function (with symptoms such as swelling from fluid retention and high blood pressure)
- hearing loss
- an allergic reaction called Kounis syndrome (your child may experience symptoms such as chest discomfort, acute chest pain, faintness, headache, nausea and dyspnoea).

These are all serious side effects. Your child may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects:
- appetite loss
- nausea, vomiting, diarrhoea, abdominal pain
- headache.

Less frequent side effects:
- abnormal blood and/or urine test results
- dizziness, sensations of tingling, burning, pricking (pins and needles), or numbness of the skin, asthenia (unusual tiredness or weakness)
- bloating, excess gas (wind), indigestion
- ringing in the ears
- abnormal liver test results
- skin rashes or other skin conditions
- skin blisters in a clustered arrangement on the face and possibly perineum, that may spread to the limbs, trunk, hands, feet, and scalp (linear IgA bullous disease)
- fatigue and asthenia
- false positive blood test (direct Coombs test).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
By reporting side effects, you can help provide more information on the safety of DYNACEF SUSPENSION. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store DYNACEF SUSPENSION
Store all medicines out of reach of children.

Before reconstitution:
Store at or below 25 °C, protect from light and humidity.

After reconstitution:
Use within 10 days. Store in a refrigerator (2 - 8 °C).
Shake well before use.
Keep the bottle tightly closed. Discard any unused portion. Do not freeze.
Do not use after the expiry date stated on the carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What DYNACEF SUSPENSION contains:
Each 5 mL of suspension contains cefpodoxime proxetil equivalent to cefpodoxime 40 mg.

The other ingredients are:
Anhydrous citric acid (for pH adjustment), artificial banana flavour spray dry, aspartame, hydroxypropyl cellulose, maize starch, microcrystalline cellulose & carboxymethyl cellulose sodium, silica colloidal anhydrous, sodium benzoate, Spectracol yellow iron oxide, sucrose.

Directions for Reconstitution of the Suspension:
Remove the screw cap by simultaneously pushing and turning it. Remove the tear-tab and discard. Add 27,0 mL water in to the dry powder for the 50 mL suspension. Add 54,0 mL water in two equally divided portions to the dry powder for the 100 mL suspension. Shake well after each addition.
See section 3 – How to use DYNACEF SUSPENSION.

What DYNACEF SUSPENSION looks like and contents of the pack
Powder for oral suspension.
Powder: Almost white to pale yellow coloured powder.
Reconstituted solution: Off-white to pale yellow suspension with characteristic fruity odour.

Translucent HDPE bottle with a white polypropylene 28 mm cap (child resistant, with foil seal peelable liner), containing powder for reconstitution up to 50 mL or 100 mL of suspension, contained in a printed outer carton.

Holder of Certificate of Registration
Pharma Dynamics (Pty) Ltd
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pharma dynamics

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S4

DYNACEF SUSPENSION 40 mg/5 mL, poeier vir orale suspensie
Kefpodoksiem
DYNACEF SUSPENSION bevat suiker (sukrose 2,46 g per 5 mL).
Bevat versoeter (aspartaam 20 mg/5 mL).

Lees hierdie hele inligtingsblad deeglik deur, voordat u begin om DYNACEF SUSPENSION te neem
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige, of ander gesondheidsorgverskaffer.
- DYNACEF SUSPENSION is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

Wat hierdie inligtingsblad bevat

1. Wat DYNACEF SUSPENSION is en waarvoor dit gebruik word
DYNACEF SUSPENSION behoort aan die antibiotiese groep medisyne, bekend as kefalosporiene.

DYNACEF SUSPENSION word gebruik vir die behandeling van:
- oorinfeksie
- tonsilitis, keelinfeksie (faringitis)
- pneumonie.

2. Wat u nodig het om te weet, voordat u DYNACEF SUSPENSION toedien
Moet nie DYNACEF SUSPENSION toedien:
- indien u kind hipersensitief (allergies) is vir ander kefalosporien antibiotika, penisillien, enige ander beta-laktaam klas antibiotika, of vir enige van die ander bestanddele van DYNACEF SUSPENSION nie (sien afdeling 6)
- DYNACEF SUSPENSION moet nie aan kinders met fenielketonurie toegedien word nie ('n skaars oorerflike versteuring, wat veroorsaak dat 'n aminosuur wat fenielalanien genoem word, in u liggaam opbou), aangesien die formule aspartaam bevat
- indien u kind jonger as 1 jaar oud is nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met DYNACEF SUSPENSION:
- DYNACEF SUSPENSION moet omsigtig gebruik word deur pasiënte wie oor die algemeen allergies is. Vertel asseblief u dokter van al die vorige allergiese reaksies wat u kind ervaar het, veral teenoor medisyne
- wees versigtig indien u kind allergies is vir penisillien antibiotika, aangesien hy/sy 'n groter kans het om ook allergies te wees vir kefalosporiene (insluitend DYNACEF SUSPENSION)
- indien u kind 'n toestand genaamd kolitis het, of ooit gehad het (inflammasie van die dikderm, met simptome soos abdominale pyn, diarree en koors), of indien u kind diarree ontwikkel, veral indien dit erg of aanhoudend voorkom, terwyl DYNACEF SUSPENSION gebruik word. Dit mag 'n aanduiding van inflammasie van die dikderm (kolitis) wees. Raadpleeg asseblief u dokter onmiddellik
- indien u kind nierprobleme het, mag dit nodig wees om sy/haar dosis aan te pas
- indien u kind sekere bloed-, of urientoetse ondergaan, aangesien DYNACEF SUSPENSION met die resultate mag inmeng
- indien u kind simptome soos konvulsies, verwarring, bewussynsversteurings, of abnormale bewegings ervaar (veral by kinders met nierprobleme, of die wie meer medisyne toegedien is as wat benodig word), kontak u dokter of gesondheidsorgverskaffer onmiddellik.

Ander medisyne en DYNACEF SUSPENSION
Vertel altyd u gesondheidsorgverskaffer indien u enige ander medisyne neem (Dit sluit aanvullende, of tradisionele medisyne in). Sekere medisyne mag 'n wisselwerking met DYNACEF SUSPENSION toon. In hierdie gevalle, mag dit nodig wees om die dosis te verander, of die behandeling van een van die medisyne te onderbreek.
DYNACEF SUSPENSION werk beter, wanneer dit saam met kos geneem word.

Medisyne wat 'n interaksie met DYNACEF SUSPENSION mag toon is:
- medisyne wat gebruik word om ulkusse te behandel, soos ranitidien, of simetidien en teensuurmiddels (gebruik om indigestie te behandel, soos aluminiumhidroksied, natriumbikarbonaat), mag die werking van DYNACEF SUSPENSION vertraag
- pentagastrien (medisyne wat gebruik word om maagsuuruitskeiding te stimuleer), mag die effek van DYNACEF SUSPENSION versterk
- probenesied (gebruik vir die behandeling van jig), mag die bloedvlakke van DYNACEF SUSPENSION verhoog en die moontlikheid van newe-effekte laat toeneem
- teenstolmiddels soos warfarien (gebruik om die bloed te verdun), mag die risiko vir bloeding verhoog
- maak asseblief seker dat u dokter bewus is dat u kind DYNACEF SUSPENSION neem, indien hy/sy enige toetse moet ondergaan (bloed, urine, of diagnosties), aangesien hierdie medisyne met die toetsresultate mag inmeng
- sommige diuretika (watertablette bv. furosemied), wat gebruik word om die volume urine wat u passeer te verhoog, mag u niere aantas
- aminoglikosied antibiotika (bv. gentamisien) (gebruik om infeksies te behandel), mag die manier waarop u niere werk, beïnvloed
- aangesien teenstolmiddels die risiko vir bloeding mag verhoog, mag u dokter dit nodig ag om die verhoogde verhouding van bloedstollingstyd te monitor, terwyl u kind DYNACEF SUSPENSION neem.

DYNACEF SUSPENSION saam met kos en drinkgoed
DYNACEF SUSPENSION moet na 'n maaltyd geneem word.

Swangerskap, borsvoeding en fertiliteit
Nie van toepassing nie.

Bestuur en die hantering van masjiene:
Indien ongunstige effekte soos duiseligheid, of ensefalopatie (wat 'n aanval, verwarring, bewussynsversteurings, of abnormale bewegings mag insluit) voorkom, moet pasiënte nie bestuur, of masjiene hanteer nie.

Dit is nie altyd moontlik om te voorspel tot watter mate DYNACEF SUSPENSION met die daaglikse aktiwiteite van 'n pasient sal inmeng nie. Pasiente moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak, totdat hulle bewus is tot watter mate DYNACEF SUSPENSION hulle beinvloed nie.

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DYNACEF SUSPENSION bevat aspartaam (20 mg/5 mL) en sukrose en natriumbensoaat.
Aspartaam:
DYNACEF SUSPENSION moet nie deur pasiënte met fenielketonurie geneem word nie, aangesien een van die metaboliese produkte, fenielalanien is (sien Moet nie DYNACEF SUSPENSION neem).

Sukrose:
Indien u dokter u ingelig het dat u 'n onverdraagsaamheid teenoor sommige suikers toon, kontak u dokter voordat u hierdie medikasie neem. Bevat sukrose. Dit moet in ag geneem word by pasiënte met diabetes mellitus.

Natriumbensoaat:
DYNACEF SUSPENSION bevat 10 mg natriumbensoaat per 5 mL suspensie, wat gelykstaande is aan 0,2 %.
Natriumbensoaat mag geelsug by pasgebore babas vererger (tot en met 4 weke oud).

3. Hoe om DYNACEF SUSPENSION te neem
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Gebruik DYNACEF SUSPENSION altyd presies soos deur u dokter aanbeveel word. U moet u dokter of apteker raadpleeg indien u onseker is.
DYNACEF SUSPENSION moet na 'n maaltyd geneem word.

Kinders:
Die gemiddelde dosis is 8 mg/kg/dag, toegedien as twee doserings elke 12 uur, saam met maaltye. U dokter sal die dosis aanpas, in ooreenstemming met die kind se gewig.

Die volgende mag gebruik word as 'n doseringsriglyn:
- kinders wat tussen 10 en 15 kg weeg, is die dosis 5 mL elke 12 uur
- kinders wat 15 kg of meer weeg, is die dosis 10 mL elke 12 uur.

Skud die bottel voor gebruik. Vir hersamestellingaanwysings, verwys na afdeling 6.

Nierversteurings:
Indien u kind 'n nierversteuring het, sal hy/sy 'n laer dosis as normaal ontvang. U dokter sal die gepaste dosis, in ooreenstemming met sy/haar toestand, bepaal.

DYNACEF SUSPENSION moet nie aan kinders met fenielketonurie toegedien word nie, aangesien die formule aspartaam bevat (kyk Moet nie DYNACEF SUSPENSION neem).

Toediening van DYNACEF SUSPENSION aan kinders jonger as een jaar oud, word tans nie aanbeveel nie, aangesien veiligheid nog nie vasgestel is nie.

U dokter sal u vertel vir hoe lank u kind se behandeling met DYNACEF SUSPENSION sal duur. Indien u onder die indruk is dat die effek van DYNACEF SUSPENSION té sterk, of té swak is, vertel u dokter of apteker.

Indien u meer DYNACEF SUSPENSION toedien as wat u moes:
In die geval van oordosering, raadpleeg u dokter of apteker.
Indien beide nie beskikbaar is nie, kontak die naaste hospitaal, of gifbeheersentrum.
Neem hierdie inligtingsblad en die oorblywende suspensie saam met u, sodat die dokter weet watter medisyne u kind geneem het.

Simptome van oordosering mag die volgende insluit:
- enige van die simptome soos beskryf onder Newe-effekte, insluitend sentrale senuweestelseltoksisiteit (met simptome wat angstigheid, duiseligheid, mondgevoelloosheid, lighoofdigheid, gelui, of gegons in die ore en konvulsies, insluit) en breinfunksieprobleme (met simptome soos geheueverlies, persoonlikheidsveranderinge, aanvalle en spiertrekkings)

Indien u vergeet om DYNACEF SUSPENSION toe te dien:
Indien u vergeet om DYNACEF SUSPENSION toe te dien, doen dit so gou as wat u onthou, op dieselfde dag. Indien u nie die dosis op dieselfde dag toedien nie, gee die normale dosis die volgende dag. Moet nie 'n dubbeldosis toedien, om op te maak vir die vergete, individuele doserings nie.

Indien u die gebruik van DYNACEF SUSPENSION staak
Dit is belangrik dat u die behandelingskursus volhou, selfs al begin u kind beter voel na 'n paar dae.

4. Moontlike newe-effekte
DYNACEF SUSPENSION kan newe-effekte hê.
Nie alle newe-effekte wat vir DYNACEF SUSPENSION aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongewenste effekte ervaar, terwyl u DYNACEF SUSPENSION gebruik, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgdeskundige vir advies.

Indien enige van die volgende gebeur, staak die gebruik van DYNACEF SUSPENSION en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat sluk of asemhaling mag bemoeilik, skok
- uitslag, of gejeuk
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u kind dit ondervind, kon hulle 'n ernstige allergiese reaksie teenoor DYNACEF SUSPENSION ervaar het. U kind mag dringende mediese aandag, of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- hepatitis (lewerinflammasie) en ander lewerprobleme, insluitend geelsug (simptome mag die volgende insluit: naarheid, braking, maagpyn, aptytverlies, moegheid, vergeling van die vel of wit gedeeltes van u oë, donker urine), lewerbesering, verhoging in lewerensieme
- 'n erge infeksie van die dermwand, gekenmerk deur diarree, koors en buikpyn. Dit mag iets soos "Pseudomembraneuse kolitis" wees, bloed in die stoelgang
- blaasvorming, afskilfering, of bloeding op enige gedeelte van u vel, gepaardgaande met, of sonder 'n uitslag (insluitend u lippe, oë, mond, neus, geslagsdele, hande, of voete), griep-soortige simptome (koors, koue rillings, of seer spiere), wat simptome van 'n ernstige velreaksie is (Steven-Johnson-Sindroom of toksiese epidermale nekrolise (TEN)). Dit mag noodlottig wees
- veluitslag, of velletsels met 'n pienk/rooi ring en 'n bleek kern, wat jeukerig, skubberig, of met vloeistof gevul mag wees. Die uitslag mag veral op u palms of voetsole voorkom. Hierdie mag tekens van 'n ernstige velreaksie, wat 'erythema multiforme' genoem word, wees
- pankreatitis (inflammasie van die pankreas) (simptome mag boonste abdominale pyn, wat na die rug uitstraal; geswelde en gevoelige abdomen; naarheid en braking, koors en 'n vinniger hartklop, insluit)
- u kind kry infeksies makliker as gewoonlik. Dit kan wees weens 'n bloedversteuring en is meer waarskynlik indien hy/sy DYNACEF SUSPENSION langdurig gebruik
- superinfeksie ('n tweede infeksie wat voorkom tydens die verloop van die bestaande infeksie deur ander bakterieë of organisms wat weerstandig is teenoor DYNACEF SUSPENSION), insluitend swaminfeksies, soos orale, of vaginale sproei
- koue rillings, moegheid, ongewone bleek velkleur, asemnood, vinnige hartklop, of donkerkleurige urine. Dit mag tekens van 'n ernstige tipe bloedarmoede wees
- bloedversteurings, wat veroorsaak dat u kind meer geneig is tot infeksies, vinnig moeg word, of baie dikwels kneus
- u kind kneus makliker as gewoonlik, of mag 'n pynlike uitslag van donkerrooi kolletjies onder die vel toon, wat nie verdwyn as u daarop druk nie (purpura). Dit mag voorkom weens 'n ernstige bloedprobleem
- aanvalle, sentrale senuweestelseltoksisiteit (met simptome wat angstigheid, duiseligheid, mondgevoelloosheid, lighoofdigheid, gelui of gegons in die ore en konvulsies, insluit)
- min of geen urine, wanneer u probeer urineer nie, afname in nierfunksie (met simptome soos swelling weens vloeistofretensie en hoë bloeddruk)
- gehoorverlies
- 'n allergiese reaksie wat Kounis-sindroom genoem word (u kind mag simptome soos borsongemak, akute borspyn, duiseligheid, hoofpyn, naarheid en asemnood ervaar).

Hierdie is alles ernstige newe-effekte. U kind mag dringende mediese aandag benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom:
- aptytverlies
- naarheid, braking, diarree, buikpyn
- hoofpyn.

Minder algemene newe-effekte:
- abnormale bloed en/of urientoetsresultate
- duiseligheid, sensasie van tinteling, branderigheid, prikkeling (spelde en naalde), of gevoelloosheid van die vel, astenie (ongewone moegheid of swakheid)
- voel opgeblase, oormaat winderigheid (wind), slegte spysvertering
- gelui in die ore
- abnormale lewertoetsresultate
- veluitslae, of ander veltoestande
- velblase in 'n trosrangskikking op die gesig en moontlik perineum, wat mag versprei na die ledemate, bolyf, hande, voete en kopvel (lineêre IgA bulleuse siekte)
- uitputting en astenie
- vals positiewe bloedtoets (direkte Coombs toets).

Indien u enige newe-effek opmerk, wat nie in hierdie inligtingsblad genoem word nie, raadpleeg asseblief u dokter of apteker.

Aanmelding van newe-effekte
Indien u newe-effekte opmerk, praat met u dokter, apteker, of verpleegkundige. U kan ook newe-effekte by SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op die SAHPRA webtuiste gevind kan word, aanmeld. U kan help om meer inligting aangaande die veiligheid van DYNACEF SUSPENSION te bekom, deur newe-effekte aan te meld. U kan ook 'n e-pos direk aan die maatskappy stuur by: pharmacovigilance@pharmadynamics.co.za, om die veiligheid van die medisyne te verseker.

5. Hoe om DYNACEF SUSPENSION te bewaar
Bewaar alle medisyne buite die bereik van kinders.

Voor hersamestelling:
Bewaar teen of benede 25 °C, beskerm teen lig en humiditeit.

Na hersamestelling:
Gebruik binne 10 dae. Bewaar in 'n yskas (2 - 8 °C).
Skud goed voor gebruik.
Hou die bottel dig geseël. Gooi enige ongebruikte gedeelte weg.
Moenie vries nie.
Moet nie gebruik na die vervaldatum wat op die bottel aangedui word nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette), weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat DYNACEF SUSPENSION bevat:
Elke 5 mL suspensie bevat kefpodoksiemproksetil, gelykstaande aan kefpodoksiem 40 mg.

Die ander bestanddele is:
Aspartaam, hidroksiepropielsellulose, kunsmatige piesanggeur (sproeidroog), mieliestysel, mikrokristallyne sellulose & natriumkarboksimetielsellulose, natriumbensoaat, Spectracol geel ysteroksied, sukrose, watervrye kolloïdale silika, watervrye sitroensuur (vir pH-aanpassing).

Aanwysings en Hersamestelling van die Suspensie:
Verwyder die skroefdoppie, deur dit gelyktydig te druk en te draai. Verwyder die skeuroortjie en gooi dit weg. Voeg 27,0 mL water in die droë poeier vir die 50 mL suspensie. Voeg 54,0 mL water in twee gelyke dele by die droë poeier vir die 100 mL suspensie. Skud goed na elke byvoeging.
Sien afdeling 3 – Hoe om DYNACEF SUSPENSION te gebruik.

Hoe DYNACEF SUSPENSION lyk en die verpakkingsinhoud
Poeier vir orale suspensie.
Poeier: Naaswit, tot liggeel-kleurige poeier.
Hersaamgestelde oplossing: Naaswit tot liggeel suspensie, met 'n kenmerkende vrugtereuk.

Deurskynende HDPE bottel, met 'n wit polipropileen 28 mm doppie (peuterbestand, met 'n foelie aftrekbare bedekking). Bevat poeier vir hersamestelling tot en met 50 mL of 100 mL suspensie, in 'n gedrukte buitenste kartonhouer.

Eienaar van die Registrasiesertifikaat
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